

EndoSequence® BC Sealer™ & BC Sealer™ HiFlow™ Instructions for Use

Rx Only

For Dental Use Only

CONTRAINDICATION

- Do not use EndoSequence® BC Sealer/BC Sealer HiFlow™ in patients with a known allergy to any of the product's ingredients. An allergic reaction may require re-treatment.

PRECAUTIONS

- Discard the disposable BC Tips after each application. Potential cross-contamination may occur if single use disposable BC Tips are re-used. Do not re-use the BC Tips.
- EndoSequence® BC Sealer/BC Sealer HiFlow™ and the disposable BC Tips are not designed to be sterilized. Please do not sterilize EndoSequence® BC Sealer/BC Sealer HiFlow™ or the disposable BC Tips. Failure to follow these instructions could damage the product and/or distort the BC Tips, resulting in procedural delays or user inconvenience.
- Cleaning:**
 - Disinfect the exterior surfaces of the syringe and syringe cap (once it is tightly sealed onto the syringe) prior to storage to reduce the risk of cross-contamination.
 - The EndoSequence® BC Sealer/BC Sealer HiFlow™ syringe should be mantled with a hygienic single-use barrier sleeve for infection control for direct intra-oral use.
- Ensure there is continuous flow of EndoSequence® BC Sealer/BC Sealer HiFlow™ and the placement site is completely filled. Failure to do so may result in procedural delays.
- Ensure that any bleeding is under control prior to placing EndoSequence® BC Sealer/BC Sealer HiFlow™, as the material may wash out of the placement site and require re-treatment.

STORAGE

- EndoSequence® BC Sealer/BC Sealer HiFlow™ must be stored in a dry area at room temperature.
- Closely follow the recommended storage conditions. Failure to do so will cause the material to prematurely set resulting in re-treatment of material placement or user inconvenience. To avoid prematurely inducing the setting process closely follow these guidelines:
 - Use the syringe cap to keep the syringe tightly closed when the material is not in use. Keep the syringe cap free from moisture.
 - Keep EndoSequence® BC Sealer/BC Sealer HiFlow™ tightly sealed in its pouch and store at room temperature in a dry area to avoid moisture contact.

WARNINGS

- Use personal protective equipment to avoid contact of EndoSequence® BC Sealer/BC Sealer HiFlow™ with the skin, mucus membranes and eyes. Unset EndoSequence® BC Sealer/BC Sealer HiFlow™ may cause irritation. Please refer to the Safety Data Sheet (SDS) for the first aid procedures.
- Do not use excessive force to apply the material into the root canal as this may cause patient sensitivity, discomfort and/or pain, or breakage of the syringe plunger.
- Always inspect the syringe prior to application into the root canal site. Using a syringe with illegible reference markings could lead to overfilling or underfilling of the root canal site.
- EndoSequence® BC Sealer/BC Sealer HiFlow™ has not been tested in pregnant women or nursing mothers.
- Procedural delays or user inconvenience may be experienced if the disposable BC Tip is not inspected prior to use. If EndoSequence® BC Sealer/BC Sealer HiFlow™ does not flow out of the disposable BC Tip or if the BC Tip feels stiff, discard the BC Tip and use a new BC Tip.
- Always check the expiration date of the product to prevent procedural delays or user inconvenience (e.g. material becomes brittle or will not set).
- Overfilling the root canal may lead to patient sensitivity, foreign body inflammation, maxillary sinus aspergillosis, paresthesia of anesthesia due to nerve impingement or may require surgical removal of the overfill.
- Carefully read package labeling to ensure use of the appropriate bioceramic material. Failure to do so may cause user or patient inconvenience.
- Multiple continuous applications of material using the syringe delivery system may cause hand fatigue.

- Please ensure that the carton and pouch have not been opened or damaged, as this indicates that the barriers have been breached.

ADVERSE REACTION

- If the patient should experience any unusual pain, swelling or discomfort orally or in the jaw region following treatment of EndoSequence® BC Sealer/BC Sealer HiFlow™, please advise the patient to seek medical attention.

INTERACTIONS WITH OTHER DENTAL MATERIALS

- None known

EQUIPMENT

- Hand file(s)
- Moist cotton balls or swabs
- Gutta percha points and paper points

PRODUCT DESCRIPTION

EndoSequence® BC Sealer/BC Sealer HiFlow™ Injectable Root Canal Sealer is a convenient premixed ready-to-use, injectable white hydraulic cement paste developed for permanent root canal filling and sealing applications. EndoSequence® BC Sealer/BC Sealer HiFlow™ is an insoluble, radiopaque and aluminum-free material based on a calcium silicate composition, which requires the presence of water to set and harden. EndoSequence® BC Sealer/BC Sealer HiFlow™ does not shrink during setting and demonstrates excellent physical properties. EndoSequence® BC Sealer/BC Sealer HiFlow™ is packaged in a preloaded syringe and is supplied with disposable BC Tips.

INDICATIONS FOR USE

- Permanent obturation of the root canal following vital pulp-extirpation.
 - Permanent obturation of the root canal following removal of infected or necrotic pulp and placement of intracanal dressings.
- EndoSequence® BC Sealer/BC Sealer HiFlow™ is suitable for use in the single cone and lateral condensation technique.

WORKING TIME

No mixing is required. EndoSequence® BC Sealer/BC Sealer HiFlow™ can be applied immediately and introduced directly into the root canal. The working time can be more than 30 minutes at room temperature.

SETTING TIME

Setting time is 4 hours. However, in very dry root canals, the setting time can be more than 10 hours.

COMPOSITION

Zirconium oxide, calcium silicates, calcium hydroxide, calcium phosphate monobasic and filler agents.

INTERACTIONS

The setting time of EndoSequence® BC Sealer/BC Sealer HiFlow™ is dependent upon the presence of moisture in the dentin. The setting reaction can proceed quickly in root canals, which have been inadequately dried. The amount of moisture required for the setting reaction to occur, reaches the root canal by means of the dentinal tubules. Therefore, it is not necessary to add moisture in the root canal prior to placing the material.

REMOVAL OF ROOT CANAL FILLING

Conventional techniques can be used for the removal of EndoSequence® BC Sealer/BC Sealer HiFlow™ as used in combination with gutta percha points. Piezo Electric Ultrasonics (with water spray) can also be used.

DIRECTIONS FOR USE:

- Prior to the application of EndoSequence® BC Sealer/BC Sealer HiFlow™, thoroughly prepare and irrigate the root canal using standard endodontic techniques.
- Dry the canal as you normally would using paper points.
- Sealer Delivery Methods:** both of the following sealer delivery methods are effective. The clinician should utilize whichever method they are most comfortable with:
 - Traditional Method:**
Coat the primary gutta percha point or a small hand file with EndoSequence® BC Sealer/BC Sealer HiFlow™ (extra-orally) and use the point or file to apply EndoSequence® BC Sealer/BC Sealer HiFlow™ to the canal walls.

EndoSequence® BC Sealer™ & BC Sealer™ HiFlow™ Instructions for Use**b. BC Tip Delivery Method:**

Remove the syringe cap from the EndoSequence® BC Sealer/BC Sealer HiFlow™ syringe. Securely attach a disposable BC Tip with a clockwise twist to the hub of the syringe. The disposable BC Tips are flexible and can be bent to facilitate access to the root canal. Insert the tip of the syringe into the canal no deeper than the coronal one third (1/3). Gently and smoothly dispense a small amount (1-2 reference markings) of EndoSequence® BC Sealer/BC Sealer HiFlow™ into the root canal by compressing the plunger of the syringe. Using a #15 hand file or any comparable hand file, lightly coat the canal walls with the existing EndoSequence® BC Sealer/BC Sealer HiFlow™ in the canal. Then coat the master gutta percha cone with a thin layer of EndoSequence® BC Sealer/BC Sealer HiFlow™ and very slowly insert it into the canal. The master gutta percha cone will carry sufficient EndoSequence® BC Sealer/BC Sealer HiFlow™ to the apex.

Note: The precise fit of the gutta percha master cone creates excellent hydraulics and for that reason it is recommended that the practitioner use a small amount of EndoSequence® BC Sealer/BC Sealer HiFlow™. Furthermore, it is also important to insert the master cone very slowly to its final working length. If using a warm vertical technique, see the instructions for use for your powered heat source.

4. If desired, place additional gutta percha points into the canal using standard condensation techniques.
5. Using a heat source, burn off the gutta percha cones at the orifice, apply a slight amount of vertical condensation, and remove any excess EndoSequence® BC Sealer/BC Sealer HiFlow™ with a moist cotton ball or swab.
6. EndoSequence® BC Sealer/BC Sealer HiFlow™ will remain part of the permanent root canal filling.
7. After each application, remove the disposable tip from the syringe with a counterclockwise twist to the hub of the syringe and discard. Clean the outside of the syringe and remove any excess paste, place the syringe cap tightly onto the syringe hub, and place the syringe into the foil pouch and ensure to seal the pouch. Store the pouch in a dry area at room temperature.

U.S. Patent Nos.: 7,553,362, 7,575,628, 8,343,271, 8,475,811

European Patent Nos.: 1861341 A4, 2142225 B1

Glossary of Symbols: www.Brasselerusadental.com/resources

Manufactured for
Brasseler U.S.A. Dental, LLC
One Brasseler Blvd.
Savannah, GA 31419 USA
Telephone 800-841-4522